UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,776	06/19/2003	Scott Russell Burge		5990

7590 04/11/2005

Scott Russell Burge
8869 South Myrtle Avenue
Tempe, AZ 85284

EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,776	BURGE, SCOTT RUSSELL	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *1-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Election of claims 5-9 without traverse, filed on 02/28/05 is acknowledged. Claims 1-4 are withdrawn from consideration.

Specification

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing "a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the invention.

The specification does not provide any working example of Fujiwara-type reaction involving pyridine-2,6-dicarboxylic acid (dipicolinic acid, DPA) and any of "gem polychlorinated hydrocarbons" in the presence of a strong base. Anderson et al. (US 4,929,562) disclose detecting "gem-polyhalogenated hydrocarbons" based on Fujiwara reaction involving ~90% pyridine (or its derivatives, with no particular derivatives indicated or disclosed in the Examples) and "a hindered nitrogen base". However, the patent does not provide any indication that a pyridine derivative with two carboxyl groups in ortho-positions to nitrogen atom is capable of reacting with polyhalogenated hydrocarbons in the presence of a strong base. Moreover, according to a complex reaction scheme for Fujiwara reaction (Strategic Diagnostics Inc., Figure 1), pyridine nitrogen reacts with a halogenated carbene formed from a "gem polychlorinated hydrocarbon" and a strong base. In the case of DPA it is hard to imagine the halogenated carbene reacting with DPA nitrogen atom completely hindered by two big CO_2H-groups. Also, it is well known that carbene strongly reacts with carboxyl groups. Therefore, it can be assumed that the reaction products of DPA with polyhalogenated hydrocarbons in the presence of the hindered nitrogen base will be of a completely different nature then the products of Fujiwara

reaction, if the reaction takes place at all. The specification does not provide any evidence for forming any fluorescence of UV detectable products in the Fujiwara-type reaction involving a trace of DPA.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As it is indicated above, the specification does not provide any evidence for forming fluorescence of UV detectable products in the Fujiwara-type reaction involving a trace of DPA, or even ability to perform such reaction. The prior art does not predict with a reasonable expectancy a successful conducting Fujiwara-type reaction involving a trace of DPA and polyhalogenated hydrocarbons in the presence of the hindered nitrogen base. On the contrary, existing prior art teaching both detecting poly-halogenated hydrocarbons based on Fujiwara reaction and identifying bacterial spores by detecting DPA demonstrates a very low probability of such reaction and, correspondingly formation of fluorescence or UV-detectable products of Fujiwara reaction. As it was indicated above, in the case of detecting polyhalogenated hydrocarbons using Fujiwara reaction ~90% pyridine was used for successful obtaining UV or fluorescence-detectable products. Strategic Diagnostics Inc. paper provides a complex scheme for the mechanism of the reaction and indicates that many parameters of reactions conditions, as well as the nature of participating reagents affects the reaction paths and outputs. The mechanism involves reaction of the halogenated carbene formed from polyhalogenated hydrocarbon in the presence of strong base with pyridine nitrogen, which makes the probability of such reaction for 2,6-di-carboxylic

derivative of pyridine very low. Most references describing detection of bacterial spores based on detecting DPA via fluorescence and UV involve complexation of DPA with metal ligands, such as lanthanide metals (e.g. terbium), Fe^{2+} or Ca^{2+} at carboxyl groups (see Vanderberg et al., US 6,599,715; Robinson, US 2003/0108981; Warth, Anal. Chem., 1983; Sacks, Appl. Envir. Microbiol., 1990; Hindle et al.. Analyst, 1999; Nudelman et al. Proceed. SPIE, 1999; Bronk et al. Proceed. SPIE, 2000). None of the references indicate a reaction of DPA with halogenated hydrocarbons to yield UV- or fluorescence-detectable products.

The specification does not provide any examples of Fujiwara-type reaction performed for DPA, neither does it indicate any reaction conditions for obtaining detectable products. Therefore, the claimed invention is not enabled by the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites, "a method of detecting of a bacillus extracting an analyzing pyridine-2,6 dipicolinic acid, the method comprising ...". First of all, there is no such compound as "pyridine-2,6 dipicolinic acid". There is compound "pyridine-2,6-dicarboxylic acid", which is called dipicolinic acid, or DPA. Further, from the claim it is not clear, if "extracting" and "analyzing" are the active steps of the method. In order to detect bacillus, DPA should be extracted, and therefore the extraction should be an active step of the method, rather than a definition in the claim preamble. Further, it is not clear, which "one of the products of the reaction" is detected, if "a reaction product" is formed.

Claim 6 recites bromoform as a "gem polychlorinated hydrocarbon". Bromoform ($CHBr_3$) does not contain any Cl atom, not mentioning multiple Cl atoms, and therefore cannot be recited as "gem polychlorinated hydrocarbon".

In claim 8 it is unclear, what "other phenoxides" might be, and if all possible phenoxides can be used for the reaction, then why thiophenoxide does not belong to the "other phenoxides"?

Claim 9 comprises two sentences, which is not the right format for the claim. Also, the claim contains a number of incorrectly written chemical names. Furthermore, it is not clear, what is an organic base modifier, and what is the reagent, as no reagent was recited in claim 5. The claim is completely unclear.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena Gakh

4/6/05

YELENA GAKH
PRIMARY EXAMINER